

1 Wellness Way
Canton, MA 02021
point32health.org

The Honorable Xavier Becerra
Secretary of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

The Honorable Julie Su
Acting Secretary of Labor
200 Constitution Avenue, N.W.
Washington, DC 20210

The Honorable Janet Yellen
Secretary of the Treasury
1500 Pennsylvania Avenue, N.W.
Washington, D.C. 20220

RE: Request for Information; Coverage of Over-the-Counter (OTC) Preventive Services

Dear Secretaries Becerra, Su, and Yellen:

Point32Health welcomes the opportunity to provide insights concerning the Request for Information; Coverage of Over-the-Counter (OTC) Preventive Services, as published by the Internal Revenue Service (IRS), Department of Labor (DOL), and Department of Health and Human Services (HHS) – collectively referred to as the "Tri-Agencies" – on October 4, 2023, in the Federal Register.

Who We Are

Point32Health is a leading health and well-being organization, delivering an ever-better healthcare experience to everyone in our communities. Building on the quality, nonprofit heritage of our founding organizations, Tufts Health Plan and Harvard Pilgrim Health Care, we leverage our experience and expertise to help people find their version of healthier living through a broad range of health plans and tools that make navigating health and wellbeing easier.

Our programs take a 360-degree view of health for our members -- no matter their age, health, identity, or income. Our foundation works with communities to support, advocate, and advance healthier lives for everyone and our Institute works to improve population health. We use empathy to understand what's important to those we serve, always making their priorities our own. We work to guide and empower people by bringing together wide-ranging partners and perspectives to create new approaches that make a real difference for both our industry and our 2.2 million members across the United States. We are proud that our Harvard Pilgrim Health Care Commercial Combined HMO, PPO and POS plans in Massachusetts and Maine, our Exchange HMO plans in Massachusetts and Maine, as well as Tufts Health Plan's Medicaid and Exchange HMO plans, have received full Health Equity Accreditation from the National Committee for Quality Assurance (NCQA). We are consistently a highly rated Medicare Advantage plan. For eight years, from Star Year 2016 to Star Year 2023, our Tufts Medicare Preferred HMO plan received a 5-star rating from the Centers for Medicare & Medicaid Services, the highest rating possible.

We are proud that Point32Health was recently recognized for the second year in a row as one of the 50 most community-minded companies in the nation by Points of Light, the world's largest nonprofit dedicated to volunteer service. A national standard for corporate citizenship, The Civic 50 showcases

how leading companies are incorporating social impact, civic engagement, and community integration into their practices and values.

Our Comments on the Request for Information (RFI)

In addressing the coverage of over-the-counter (OTC) preventive services, our primary focus remains ensuring that beneficiaries are at the center of any proposed changes. We advocate for a careful balance that includes:

- 1) Utilizing practical administrative structures to enable successful implementation for patients
- 2) Preserving quality of care and the affordability of overall premiums for members, and
- 3) Implementing robust measures to guard against fraud, waste, and abuse.

First, it is important to clarify, that under certain circumstances today, health plans do provide coverage for over-the-counter items. This normally occurs when an individual receives a prescription from a provider. Some examples of this can include breastfeeding supplies, tobacco cessation products, folic acid, and COVID-19 tests.

1) Utilizing Practical Administrative Structures to Enable Successful Implementation for Patients

We understand the objective of the RFI is to explore the coverage of over-the-counter preventive services without a prescription. In order to assure seamless OTC implementation for patients, it is important for the Tri-Agencies to understand the steps involved for health plans that use PBMs to administer prescription coverage. The process typically starts with a prescription that includes important identifiers like the National Drug Code (NDC). This prescription is made to the pharmacy from a provider. The PBM communicates with the pharmacy and handles the claim and checks relevant data. Pharmacy and PBM benefits software systems are often set up to process only prescribed products.

During COVID, a workaround that was developed to allow patients to receive their COVID vaccinations and antigen test kits from pharmacies at no charge – without a prescription – was the use of “standing orders”. Standing orders provide written authorization for nurses, medical assistants, and other members of the healthcare community to complete certain clinical tasks without first obtaining a specific physician order customized to a patient. A standing order can be used for medications that are given on a daily or weekly basis and can be used for immunizations, routine refills for chronic disease medications, referrals, and more. For example, a standing order can be used for over-the-counter preventive services such as contraceptives.

The CDC produces clinically detailed standing vaccine orders, which then can be signed off on by a “Medical Director (or other authorized practitioners)”. [Here](#) is an example of the Moderna Vaccine standing order. In Massachusetts during the COVID-19 emergency, plans were required to cover OTC COVID test kits, and states like California, Colorado, Connecticut, New York, and Pennsylvania created their own standing orders to allow for Rx claims to be processed. Other states used an alternative approach, where a physician licensed within the state signed a [blanket standing order](#) that covered all pharmacies in the state.

Regardless of whether or not OTC coverage is implemented through standing orders or other methods, there will be significant changes necessary for insurers and other stakeholders to make to existing systems. It is therefore, also critical that the Tri-Agencies allow adequate implementation time following the promulgation of final regulations and technical guidance. Compressed implementation timelines are likely to lead to patient frustration and cause unnecessary costs during the implementation timeframe.

Recommendation: To make this process work without any prescription, we recommend the Agencies consider the use of “standing” orders. A number of states have passed laws permitting pharmacists to prescribe certain methods of contraception, including OTC contraception, or to dispense it pursuant to a standing order or collaborative practice agreement. We encourage the Tri-Agencies to consider allowing the pharmacist to prescribe or have a standing order for certain preventive items or products.

This possible workaround would involve having the medical doctor associated with a PBM or pharmacy issue standing orders for certain over-the-counter preventive services. This would need to be facilitated by the federal government by providing clear guidelines and templates, ensuring that necessary identifiers are easily accessible, and facilitating efficient communication between healthcare providers and pharmacies. This approach would allow for existing systems to continue to be used, allow for insurance processing, and would ease patient burden at the pharmacy counter.

- Standing orders should be based on evidence-based recommendations from sources such as the USPSTF
- The standing orders should be approved and supervised by the clinic's (such as a health care facility) medical director
- The standing order should authorize designated members of the health care community such as nurses, medical assistants, or pharmacists, to assess, educate, counsel, administer, or dispense the OTC preventive service, and document the encounter
- The standing order should be communicated and coordinated with other healthcare providers, insurers, and stakeholders, and be consistent with state laws and regulations
- The standing order should specify the criteria, contraindications, dosage, frequency, and follow-up for each OTC preventive service

Another alternative could be having the administration create systems that include a list of drugs, similar to HSA/FSA eligibility, which could be processed with a specific pharmacy template without the need for a specific prescriber.

We also urge the Agencies to provide adequate time between the issuance of all final regulations *and technical guidance*.

2)Preserving Quality of Care and the Affordability of Overall Premiums for Members

As the Agencies consider OTC coverage, it is important to mitigate any potential negative impacts health outcomes. For instance, it is known that medication overload, the use of multiple medications leading to harm, is a common concern among older Americans. Nearly [two-thirds](#) of older Americans take five

or more medications (including over-the-counter drugs and supplements), putting them at greater risk for adverse drug events and hospitalizations. Research has indicated that [certain](#) types of drug regimens are more prone to dangerous drug interactions (DDIs) or have more serious DDI-related consequences, such as antiretroviral, anti-infective, and oral anticancer therapies. Most DDIs involve OTC drugs as the perpetrators. The following groups were identified to be frequently involved in DDIs: nonsteroidal anti-inflammatory drugs, food supplements, antacids, proton-pump inhibitors, H2 antihistamines, laxatives, antidiarrheal drugs, and herbal drugs.

Some examples of specific contraindications for over the counter medicines include:

- tobacco cessation pharmacotherapy – use of these drugs can lead to suicidal/homicidal ideations. Therefore, they should be approached with caution for certain individuals, such as those that already may be suffering from depression.
- folic acid supplements – may be contraindicated for dialysis or renal failure and cardiac stents, and certain cancers
- certain contraceptives (OTC progestin-only daily oral contraceptive) – these should not be used for cancer or Lupus patients. It would be important to assure that the patient is not pregnant or breastfeeding.

Bypassing the need for a prescription, also could decrease the early detection of disease. Currently, many women are motivated to visit their OBGYN for an annual wellness visit in order to review their birth control prescription. These annual visits create opportunities for early detection of other health problems (e.g. infections, cancer, etc.). Without the short term need to obtain contraception prescriptions, some women may delay or forego these visits that are critical to prevent more serious health problems.

Any increase in adverse health events also could increase overall health care costs. In addition, the scope of over-the-counter products covered could impact the cost of coverage as well. For instance, the most recent per person estimates provided by Milliman is about \$7,221 of health costs annually (based on 2021). Of this, individuals pay about \$1,133 out of pocket leaving costs of about \$507 per member per month paid by health plans. If OTC rules are not carefully constructed, they could easily exacerbate these cost elements.

Prescription birth control medication ranges from \$10 to \$50 per month. In July 2023, the FDA approved *Opill*, the first daily oral contraceptive pill available over-the-counter (OTC) without a clinician or provider's prescription. It is expected to be available in early 2024. It is not yet known what the cost of Opill will be, but if it comes in at the higher end of the range - \$50 per month, then patients who choose the Opill over their normal coverage at the low end of the range could increase their PMPM costs by \$40 or about 8 percent per month.

Additional expansions of types of OTC items could further exacerbate cost growth – for instance condoms could cost about [\\$6 per](#) month, Claritin around [\\$17](#) per month, a One A Day vitamin is about \$2.50 per month and Vitamin D3 about [\\$2.25](#) per month. While some of these costs may individually seem modest, they could rapidly accumulate. Most importantly, these are costs that reflect the current state of insurance coverage. It is unclear if manufacturers of OTC products that become covered by insurance in the future would respond by increasing prices.

In addition to the scope of OTC products, another cost differentiator would be *how* OTC products are required to be covered. Currently, preventive services are generally only covered at zero cost sharing if they are performed by an *in-network* provider. Health insurance providers play a critical role in balancing the cost of care while promoting access to necessary care. Health insurance providers' clinical care teams develop coverage policies to ensure members receive care that is safe and effective. Insurance providers also negotiate contract costs as part of our ability to offer affordable products to employers and to individuals purchasing their own coverage. To ensure safe and affordable care for members, federal regulations allow the use of medical management to promote efficient delivery of care.

Amid the COVID-19 Public Health Emergency, health insurance providers adopted direct reimbursement to members for OTC COVID-19 tests. To maintain affordability, insurers were granted the flexibility to employ various tools. For instance, they could designate preferred retailers. Plans could facilitate direct coverage by utilizing pharmacy networks or shipping programs. This allowed consumers to access tests at no cost through preferred channels or receive reimbursement for purchases at non-preferred sources (with [price capped at \\$12 per test if out of network](#)).

Recommendations: In order to minimize the impact of OTC coverage on the affordability of premiums, the Agencies should:

- Develop mechanisms to mitigate contraindications or other negative health impacts
- Continue to allow health plans to apply cost-sharing for products that are obtained “out of network” or preclude coverage
- Provide health plans with the option to limit to specified low-cost products. For example, select NDCs or generic over brand strategies to ensure affordability.
- Limit scope of OTC products, for instance to those recommended by USPSTF
- Utilize other medical management

3)Implementing robust measures to guard against fraud, waste, and abuse.

Today's health care system already faces significant problems with fraud, waste, and abuse with some research estimating that it could [exceed \\$700 billion](#) per year. Historically, specific prescriptions are important to assure that patients are pursuing medically appropriate medications. However, prescriptions also play a role in preventing fraud, waste, and abuse. The ability to bypass prescriptions and use insurance to pay for over the counter health care items could exacerbate this problem. Without a prescription, it will be difficult to monitor fraud and abuse, and stockpiling without the pharmacy and health plan's oversight. For instance, individuals could use insurance to pay for items such as tobacco cessation or condoms and then easily resell those items or give to friends or relatives.

Even more specific items – such as oral contraceptives – could be vulnerable to FWA problems. Some states with mandatory coverage requirements for contraception without a prescription require that health insurance providers cover several months' supply at a time – in some cases, up to 12 months. 12 months' supply could easily lead to waste, particularly for new users. A person may experience side effects, have difficulty with adherence, or prefer another form of contraception (or none) without using the full supply – thus making the remainder of the supply wasted product.

Other examples of OTC FWA include buying large quantities of OTC drugs that contain pseudoephedrine or using OTC drugs that contain dextromethorphan, a cough suppressant, which can be dangerous or even fatal. Pseudoephedrine is commonly found in nasal decongestants and can be misused in the illegal production of methamphetamine. Individuals may purchase these medications in bulk to extract pseudoephedrine for illicit purposes, contributing to the production of illegal drugs like methamphetamine. Dextromethorphan (DXM) abuse occurs when individuals consume these medications in excessive amounts to achieve euphoria or hallucinogenic effects. Large doses of DXM can be dangerous and lead to serious health risks, including seizures, increased heart rate, hallucinations, and, in extreme cases, even fatalities.

Certain NDCs for common OTC products, such as prenatal vitamins, reimburse at very high rates. There is potential that some pharmacists could (1) push members to take these medications without medical need, and/or (2) fill the order with the highest-reimbursing NDC. There are also concerns around telefraud related to the sale of topical creams and footbath medications through unsolicited calls and mail orders from questionable on-line pharmacies.

During the pandemic, there was variation in mail order home COVID test kits, with some kits and shipping cost priced at 3 to 4 times that of others. In cases where there is an oversupply, a pharmacy could encourage members to purchase beyond what is medically necessary in order to improve reimbursement.

Recommendations: To reduce fraud, waste and abuse, if the Agencies move forward with coverage of OTC items, we recommend:

- Health plans not be required to cover items that aren't procured through specified health plan channels
- Health plans not be required to cover products obtained in retail establishments
- The allowance of guardrails to defer fraud (e.g. limits, etc.)

We appreciate the opportunity to comment on the potential coverage of OTC products. We ask the Agencies to proceed with caution. During a time of escalating costs, the coverage of OTC products could exacerbate problems with healthcare affordability and the perennial challenge of fraud, waste, and abuse.

Sincerely,



Christina Nyquist, Vice President, Federal Affairs